

PATENT
Atty. Dkt. No. NEKT/0002

THE PENDING CLAIMS:

1-18. (Cancelled)

19. (Previously Presented) A method for spray drying a feed stock containing a pharmaceutical agent to produce particles suitable for pulmonary administration having a narrow particle size distribution comprising:

providing a liquid feed stock comprising a pharmaceutically active agent selected from the group consisting of insulin, calcitonin, erythropoietin (EPO), Factor VIII, Factor IX, ceredase, cerezyme, cyclosporine, granulocyte colony stimulating factor (GCSF), alpha-1 proteinase inhibitor, elcatonin, granulocyte macrophage colony stimulating factor (GMCSF), growth hormone, human growth hormone (HGH), growth hormone releasing hormone (GHRH), heparin, low molecular weight heparin (LMWH), interferon alpha, interferon beta, interferon gamma, interleukin-2, luteinizing hormone releasing hormone (LHRH), somatostatin, octreotide, vasopressin analog, follicle stimulating hormone (FSH), insulin-like growth factor, insulintropin, interleukin-1 receptor antagonist, interleukin-3, interleukin-4, interleukin-6, macrophage colony stimulating factor (M-CSF), nerve growth factor, parathyroid hormone (PTH), thymosin alpha 1, IIb/IIIa inhibitor, alpha-1 antitrypsin, respiratory syncytial virus antibody, cystic fibrosis transmembrane regulator (CFTR) gene, deoxyribonuclease (Dnase), bactericidal/permeability increasing protein (BPI), anti-CMV antibody, interleukin-1 receptor, 13-cis retinoic acid, pentamidine isethionate, albuterol sulfate, metaproterenol sulfate, beclomethasone dipropionate, triamcinolone acetamide, budesonide acetonide, ipratropium bromide, flunisolide, fluticasone, cromolyn sodium, and ergotamine tartrate;

forcing said liquid feed stock into a manifold defined between a vibratable element and a plate and forcing the feed stock through the plate, said plate comprising holes of at least one predetermined diameter, in order to produce liquid droplets;

drying said droplets in a gas stream to produce dried particles comprising a mass median aerodynamic diameter of less than 10 microns and a particle size distribution wherein at least 70% of the mass of the particles have a diameter within a 4 micron range; and

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collecting said dried particles.

20. (Original) A method according to claim 19 wherein the dried particles comprise a particle size distribution wherein at least 80% of the mass of the particles have a diameter within a 4 micron range.

21. (Original) A method according to claim 19 wherein the dried particles comprise a particle size distribution wherein at least 90% of the mass of the particles have a diameter within a 4 micron range.

22. (Original) A method according to anyone of claims 19-21 wherein the dried particles have a diameter within a 3 micron range.

23. (Original) A method according to anyone of claims 19-21 wherein the dried particles have a diameter within a 1.5 micron range.

24. (Currently Amended) A method according to claim 19 further comprising vibrating said vibratable element in order to force said feed stock through the plate and produce droplets.

25. (Original) A method according to claim 24 wherein said plate is vibrated by coupling a piezoelectric element to said plate.

26. (Original) A method according to claim 19 wherein said holes comprise a predetermined diameter of less than 30 microns.

27. (Original) A method according to claim 19 wherein said plate comprises holes having a first diameter of less than 30 microns and a second series of holes having a second diameter of $\pm 50\%$ of said first diameter.

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28. (Original) A method according to claim 27 wherein said second diameter is within $\pm 20\%$ of said first diameter.

29. (Original) A method according to claim 28 wherein said first diameter is less than 10 microns.

30. (Original) A method according to claim 19 wherein said particles are porous.

31. (Previously Presented) A method according to claim 19 wherein said particles comprise a mass mean diameter less than 10 microns and a mass median aerodynamic diameter of 1-5 microns.

32. (Previously Presented) A method for spray drying a feed stock containing a pharmaceutical agent comprising:

providing a liquid feed stock comprising a pharmaceutically active agent selected from the group consisting of insulin, calcitonin, erythropoietin (EPO), Factor VIII, Factor IX, ceredase, cerezyme, cyclosporine, granulocyte colony stimulating factor (GCSF), alpha-1 proteinase inhibitor, elcatonin, granulocyte macrophage colony stimulating factor (GMCSF), growth hormone, human growth hormone (HGH), growth hormone releasing hormone (GHRH), heparin, low molecular weight heparin (LMWH), interferon alpha, interferon beta, interferon gamma, interleukin-2, luteinizing hormone releasing hormone (LHRH), somatostatin, octreotide, vasopressin analog, follicle stimulating hormone (FSH), insulin-like growth factor, insulintropin, interleukin-1 receptor antagonist, interleukin-3, interleukin-4, interleukin-6, macrophage colony stimulating factor (M-CSF), nerve growth factor, parathyroid hormone (PTH), thymosin alpha 1, IIb/IIIa inhibitor, alpha-1 antitrypsin, respiratory syncytial virus antibody, cystic fibrosis transmembrane regulator (CFTR) gene, deoxyribonuclease (Dnase), bactericidal/permeability increasing protein (BPI), anti-CMV antibody, interleukin-1 receptor, 13-cis retinoic acid, pentamidine

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isethionate, albuterol sulfate, metaproterenol sulfate, beclomethasone dipropionate, triamcinolone acetamide, budesonide acetonide, ipratropium bromide, flunisolide, fluticasone, cromolyn sodium, and ergotamine tartrate;

atomizing said feed stock in order to produce liquid droplets;

drying said droplets in a gas stream to produce dried particles comprising a mass median aerodynamic diameter of less than 10 microns and particle size distribution wherein at least 70% of the mass of the particles have a diameter within a 4 micron range; and

collecting said dried particles.